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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/425,501	10/22/1999	ROBERT MARK	GNN-005	9642

25291 7590 05/07/2002

WYETH  
FIVE GIRALDA FARMS  
MADISON, NJ 07940

EXAMINER
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CHUNDURU, SURYAPRABHA

ART UNIT	PAPER NUMBER
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1637

DATE MAILED: 05/07/2002

*Handwritten signature*

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/425,501

Applicant(s)

MARK ET AL.

Examiner

Suryaprabha Chunduru

Art Unit

1637

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 12 March 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 5-13, 16-21, 43, 44 and 49-61 is/are pending in the application.
- 4a) Of the above claim(s) 5-13 and 16-21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 43, 44 and 49-61 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_\_ 6) ☐ Other:

**DETAILED ACTION**

1. Acknowledgement is made for the request to establish continued prosecution application (CPA) (Paper NO. 20) filed on March 12, 2002. The request for CPA is accepted and is established with the status of the application as follows:

- a. the filling date of this CPA is established as 10/22/1999;
  - b. Claims 42-43 are pending. Claims 22-42 and 45-48 are canceled. New claims 49-61 are added.
2. Applicants' response to the earlier office action (Paper No. 18) filed on March 12, 2002 has been entered.

**Response to Arguments**

3. Applicant's response to the office action (Paper No.12) is fully considered and found persuasive in part.
4. The Declaration submitted under 37 C.F.R. 1.132 has been considered and found not persuasive. The Declaration argues that the Nagase et al reference is not enabled to use the nucleic acid sequence disclosed. However, with regard to the operativeness of the reference, the issue is not whether the reference enables use of the product, but rather whether the reference enables synthesis of the product. As MPEP 2121.02 notes "One of ordinary skill in the art must be able to make or synthesize" regarding operativeness of products. Here, Nagase et al. in fact synthesizes the nucleic acid, and an ordinary practitioner in molecular biology could synthesize any known sequence using a selection from any of a garden variety of extremely well known methods ranging from simple chemical synthesis to ligation to PCR amplification with 100% expectation of success.

Art Unit: 1637

5. With respect to the rejection made in the previous office action under 35 U.S.C. 102(b), Applicant's arguments with respect to claims 43-44 have been considered but are found not persuasive because (i) the declaration is not persuasive with regards to the instant claims as noted above (ii) Applicants argument that the disclosure of Nagase et al. did not enable to make and use of the sequence is not persuasive since As stated in MPEP 2121.02, "ONE OF ORDINARY SKILL IN THE ART MUST BE ABLE TO MAKE OR SYNTHESIZE", one could able to chemically synthesize the sequence, ligate and amplify the product based on the prior art information and is can make the compound operable. MPEP 2121.02 further states "a reference is presumed operable until applicant provides facts rebutting the presumption of operability. In re Sasse, 629 F.2d 675, 207 USPQ 107 (CCPA 1980). Therefore, applicant must provide evidence showing that a process for making was not known at the time of the invention.

Further, the sequence disclosed by Nagase et al. is from human brain cells. Thus, the (100%) homology shown in the earlier office action is with instant SEQ ID NO.1, but not with corn species as stated by the applicants in response to the office action.

The citations to the utility guidelines is irrelevant because the prior art is not required to be useful to anticipate. Thus the rejection is maintained herein.

#### **New issues**

5. Claims 43-44 and new claims 49-61 are pending and are considered for examination in this office action.

#### **Claim Rejections - 35 USC § 112**

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it

Art Unit: 1637

pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 49-53 and 57-59 are rejected under 35U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The current claim 49 is drawn to a genus (fragments) of Bcl-xL nucleic acid comprising a nucleic acid encoding 85% amino acid homology to SEQ ID NO: 2, claim 50 drawn to a binding domain which hybridizes to a complement of a nucleotide sequence SEQ ID NO.1 and a nucleic acid encoding Bcl-xL binding protein as shown in SEQ ID NO.1. This large genus is represented in the specification by the named SEQ ID Nos. 1 and 2. Thus, applicant has expressed possession of only one species in a genus, which comprises hundreds of millions of different possibilities. The written description guidelines note regarding such genus/species situations that "Satisfactory disclosure of a ``representative number" depends on whether one of skill in the art would recognize that the applicant was in possession of the necessary common attributes or features of the elements possessed by the members of the genus in view of the species disclosed." (See: Federal Register: December 21, 1999 (Volume 64, Number 244), revised guidelines for written description.) Here, no common elements or attributes of the sequences are disclosed in the sequences with 85% homology. With regard to the sequences, which have 85% homology, this is insufficient to demonstrate identity of Bcl-xL binding and function where no structural information regarding where in the protein the binding and function resides. The recitation of amino acids 419-559 or 429-559 in Bcl-xL binding domain in claim 53 do not specify the exact site for binding and the activity of the protein. Further no information is given regarding a methodology to determine such common elements or attributes. Further, for hybridization purposes, even a fragment of any length which comprises partial sequence of SEQ ID NO.1 hybridizes with the SEQ ID NO. 1. It is not necessary to have a full length sequence of

Art Unit: 1637

the said SEQ ID NO. 1 for hybridization. Thus, there is no description of fragments or complementary nucleic acid sequence that hybridize to SEQ ID NO. 1.

With regard to the written description, all of these claims encompass nucleic acid sequences different from those disclosed in the specific SEQ ID Nos: 1 and 2 which include modifications by permitted by the 85% language for which no written description is provided in the specification.

It is noted that in Fiers v. Sugano (25 USPQ2d, 1601), the Fed. Cir. concluded that "...if inventor is unable to envision detailed chemical structure of DNA sequence coding for specific protein, as well as method of obtaining it, then conception is not achieved until reduction to practice has occurred, that is, until after gene has been isolated...conception of any chemical substance, requires definition of that substance other than by its functional utility."

In the instant application, only the amino acid sequence of the disclosed SEQ ID Nos are described. Also, in Vas-Cath Inc. v. Mahurkar (19 USPQ2d 1111, CAFC 1991), it was concluded that:

"...applicant must also convey, with reasonable clarity to those skilled in art, that applicant, as of filing date sought, was in possession of invention, with invention being, for purposes of "written description" inquiry, whatever is presently claimed."

In the application at the time of filing, there is no record or description which would demonstrate conception or written description of any amino acids modified by addition, insertion, deletion, substitution or inversion with the disclosed SEQ ID Nos but retaining correlative function in the claimed product.

### ***Claim Rejections - 35 USC § 102***

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Art Unit: 1637

Claim 49-61 are rejected under 35 U.S.C. 102(b) as being anticipated by Nagase et al. (DNA Res., 3: 321-329, 1996).

Nagase et al. teaches the coding sequence of cDNA clone from human myeloid cell line KG-1 and brain wherein Nagase et al. disclose a cDNA clone which is identical or absolute homology (100%) to the claimed sequences in SEQ ID Nos. 1 and 2 of the instant invention (see sequence alignment from GenEmbl. and Swissprot\_39 databases). Nagase et al. also disclose that the cDNA clones showed homology to the genes that play key roles in regulation of developmental stages, apoptosis and cell-to-cell interaction (see page 321, abstract). Thus the disclosure of Nagase et al. meets the limitations in the instant claims.


No claims are allowable.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Suryaprabha Chunduru whose telephone number is 703-305-1004. The examiner can normally be reached on 8.30A.M. - 4.30P.M, Mon - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones can be reached on 703-308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-0294 for regular communications and - for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

  
Suryaprabha Chunduru  
April 30, 2002

  
JEFFREY FREDMAN  
PRIMARY EXAMINER